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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

HEMA METRICS, INC., Plaintiff, v. DUKE UNIVERSITY CLINICAL RESEARCH INSTITUTE and DUKE UNIVERSITY, Defendant.	Case No. 1:03CV00066 DB

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

INTRODUCTION

Defendants Duke University Clinical Research Institute ("DCRI") and Duke University ("Duke") hereby oppose the Motion for a Temporary Restraining Order and Preliminary

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Injunction filed on or about June 18, 2003 by plaintiff Hema Metrics, Inc. ("Hema Metrics"). Defendants appear herein by special appearance solely for the purpose of opposing Hema Metrics' motion. Defendants do not concede, and believe that the Court does not have, personal jurisdiction over either DCRI or Duke. Because, as demonstrated below, plaintiff's motion has no merit and should be denied, the Court may not be required to reach the personal jurisdiction issue. As grounds in opposition to plaintiff's motion, defendants state as follows:

STATEMENT OF FACTS[1]

DCRI is an academic research organization within Duke University and the Duke University School of Medicine. DCRI's mission is to develop and share knowledge that improves the care of patients through innovative clinical research.

Effective November 1, 1999, Duke, acting on behalf of DCRI, entered into a Clinical Trial Research Agreement ("Agreement") with Non-Invasive Medical Technologies Corporation, a company that Hema Metrics alleges was its "predecessor-in-interest." Complaint ¶ 7. (A copy of the Agreement is filed herewith as Exhibit A to the Declaration of Robert M. Califf ("Califf Decl.").) Under the Agreement, the "sponsor," Hema Metrics, contracted for Duke to "coordinate the clinical evaluation" of Hema Metrics' Crit Line monitor pursuant to a protocol agreed upon by the parties. Agreement at 1. This study was referred to as the Crit Line Intradialytic Monitoring Benefit ("CLIMB") study. *See id.* The Agreement stipulated that the research would "further the instructional and research objectives of DUKE in a matter consistent with its status as a nonprofit educational and health care institution . . . ." *Id.* The period of

[1] Unless otherwise indicated, the facts stated herein are based upon the declarations submitted herewith.

performance under the Agreement was November 1, 1999 through November 30, 2000. *Id.* § 1.4.

In order to fulfill its mission to improve patient care through innovative clinical research, DCRI must incorporate certain principles as part of any relationship it enters into with other organizations. DCRI must protect the legal rights of its faculty to discover and publicly disseminate knowledge and information that furthers DCRI's mission. Also, as an organization within Duke University, DCRI is legally required to ensure that its activities are conducted in a manner consistent with the University's status as a non-profit research, educational, and health care institution. Accordingly, where, as here, DCRI undertakes clinical trials pursuant to a contract with a commercial entity, DCRI will retain the prerogative to share with the scientific community and the general public the results of research it conducts. For this reason, DCRI generally will not agree to extended confidentiality agreements, and although it generally will recognize the ownership rights of the sponsor in the work that it commissions and the right of the sponsor to be apprised of the contents of DCRI's publications, DCRI will always retain the right to publish the results of its research without censorship or control by the sponsor.

The Agreement reflects the guiding principles of DCRI described above. Section 6.1 of the Agreement addressed ownership of the data generated by the research, providing that Hema Metrics would own the case reports, interim reports and any other reports prepared as part of the study. *See* Agreement § 6.1. However, section 6.1 also recognized Duke's right to publish the results of the research:

> DUKE shall be free to maintain copies of all such materials and to ***use the results of the research and clinical study for*** their own teaching, research, education, clinical and ***publication purposes*** including the development of research in other fields and the incorporation of such data into its common data registry of pooled data from multiple sources.

Id. (emphasis added).

Section 7 of the Agreement provided for the confidential treatment of information designated as such and required that a party receiving confidential information not disclose it without authorization from the disclosing party. *See* Agreement § 7. However, the confidentiality requirements of the Agreement were explicitly made subject to "the provisions of the section headed 'Publications' hereof . . . ." *Id.*[2]

In turn, section 8 of the Agreement set forth the parties' respective rights and obligations regarding publication. Although Hema Metrics was entitled to prior review of proposed publications, it could delay them only for purposes of filing patent applications to protect patentable information:

> SPONSOR recognizes the importance of communicating medical study or scientific data and, therefore, encourages their publication in reputable scientific journals and at seminars or conferences. DUKE shall submit to SPONSOR a copy of any proposed publication resulting from the Study at least thirty (30) days prior to submission for publication, or at least fifteen (15) days prior to submission for an abstract. If no response is received within these respective times of the date submitted to SPONSOR, it will be conclusively presumed that the publication may proceed without delay. If SPONSOR determines that the proposed publication contains patentable subject matter which requires protection, SPONSOR may require the delay of publication for a period of time not to exceed sixty (60) days for the purpose of filing patent

[2] The Agreement appears to contain a typographical error. The provision on publications is section 8, not section 10, as referenced erroneously in section 7.

> applications. DUKE and the Principal Investigators shall give SPONSOR and/or SPONSOR's personnel appropriate credit for any direct contribution made by them.

Agreement § 8. These publication rights were augmented by section 8.9 of the research protocol, which expressly provided that "[t]he results of this study may be published or presented at scientific meetings." Agreement, Appendix A at p. 17 (§ 8.9).

The research was to be conducted by six health care organizations, including Duke. Each of these "study sites" executed separate agreements. The agreement between Duke and Hema Metrics' predecessor was entitled "Clinical Study and Research Agreement" ("Study Site Agreement") and was executed in December 1999. (A copy of the Study Site Agreement is filed herewith as Exhibit B to Califf Decl.) The Study Site Agreement contained provisions on publication paralleling those in the Agreement. Pursuant to section 12 of the Study Site Agreement, the sponsor had the right to review proposed publications and to delay publication so that the parties could attempt to resolve disagreements as to content. *See* Study Site Agreement § 12. Although the parties were obligated to discuss these matters in good faith, Duke's right to publish ultimately was controlling: "This [the obligation to discuss sponsor's objections to proposed publications] ***shall not be taken to grant Sponsor any right of editorial control over publications prepared by Center [Duke]***." *Id.* (emphasis added).

The final endpoint report CLIMB study was provided by DCRI to Hema Metrics on May 30, 2002. The study compared intradialytic volume management over six months between groups of patients monitored by the Crit Line device and patients who received usual care without the monitor. There were no differences between groups with respect to multiple

secondary outcomes. In addition, Crit Line patients underwent more access related hospitalizations and experienced higher mortality than usual care patients.

For more than a year after DCRI had made the results available to Hema Metrics, the parties engaged in substantial discussion of the concerns raised by Hema Metrics as to the conduct and results of the study. DCRI responded to these concerns, but it became apparent that Hema Metrics was more interested in suppressing the results of the study than in genuinely attempting to iron out purported good faith concerns as to the way in which the research had been conducted. Furthermore, the extended delay caused by this back and forth with Hema Metrics was inconsistent with DCRI's objective of timely dissemination of the results of its work to the medical and scientific community.

Accordingly, Duke decided to submit an abstract to the American Society of Nephrology ("ASN"), reflecting its research and the clinical results for the CLIMB study, for possible inclusion as a paper or a poster at ASN's 36th Annual Meeting and Scientific Exposition on November 14-17, 2003. This conference is a premier event in the area of nephrology and is widely attended by a broad audience with an interest in this field. The abstract was a brief summary of the results of the CLIMB study, taking less than one third of a page. (A copy of the proposed abstract to be submitted is attached as Exhibit C to Califf Decl.) The deadline for submission of the abstract is 11:59 p.m., Central Standard Time, June 25, 2003. (*See* ASN web site materials concerning submission of abstracts, attached as Exhibit D to Califf Decl.)[3] The

[3] Based on Duke's prior experience, the abstract needs to be submitted in advance of this deadline, as the ASN website becomes clogged with last-minute submissions. Any internet delay in transmitting the abstract, therefore, could cause Duke to miss the deadline for submission. Accordingly, it is Duke's intention to electronically submit its abstract no later than 5:00 p.m., Eastern Standard Time, Tuesday, June 24, 2003.

abstract would be submitted to ASN through a secure internet connection. Reviewers will then review the abstract online through a secure internet connection. The ASN reviewers are required to keep all material contained in the abstracts and the abstract's "score" confidential. As a condition to serving as a reviewer, an individual must explicitly certify that "Under no circumstances will I share with others, information from abstracts or the abstracts themselves." (A copy of Abstract Reviewer contract is attached hereto as Exhibit E to Califf Decl.)

Pursuant to the terms of the Agreement, on May 12, 2003, Duke provided Hema Metrics with a copy of the abstract that it proposed to submit to ASN. This abstract was similar in content to a summary draft paper that Duke provided to Hema Metrics in March and April of 2003.

On May 19, 2003 Patrick Moriarty ("Moriarty"), the CEO of Hema Metrics, wrote to Dr. Reddan, the Principal Investigator for the CLIMB study, and raised "serious questions about and objections to it." (A copy of this letter is attached as Exhibit F to Califf Decl. ("Moriarty Letter")). Moriarty expressed essentially two concerns regarding the CLIMB study and Duke's proposed abstract. First, Moriarty suggested that the CLIMB study data was "tainted" in some way, and blamed the failure of the study on misunderstandings by the doctors and nurses involved in the study. *See* Moriarty Letter at 1. Second, Moriarty was "not comfortable" with Duke's explanation of the negative findings of the CLIMB study. *Id.* Moriarty concluded, "We do object . . . to the widespread distribution of these raw observations until they are complete and we have approved them. . . . Although you may believe you have the 'moral' obligation to disseminate the data – we believe that poor and faulty information only harms patient care.

Morality, like beauty, may be in the eyes of the beholder but our rights under the law are not." *Id.* at 2.

Duke responded in detail to Moriarty's letter. (A copy of Duke's response letter is attached as Ex. G to Califf Decl. ("Moriarty Response")). First, it offered detailed explanations as to why its study results were not flawed. *See* Moriarty Response at 1-2. Second, in response to Hema Metrics' suggestion that the study results should not be released, Duke explained:

> We . . . disagree with your contention that this data should not be disseminated until it is clearly understood. We offer that it is only through discussion and further inquiry that such explanations will be come [*sic*] apparent. These data have been accurately collected and analyzed. As you know Duke firmly believes that information gathered through careful and thorough research should be disseminated publicly to contribute the knowledge gained and foster further scientific investigation. While not all results are as expected, Duke stands by its policy to publish the results of research that it conducts. The fact that they are counter-intuitive is not a reason to suppress the results. Our results have been carefully reviewed internally by our statistical group, by the leadership of the Duke Clinical Research Institute and by our six site investigators and all have endorsed our decision to move forward with publication. We consider such publication our obligation and are concerned that delaying it further may lead to even greater adverse consequences in the long-term.

Id. at 2. Third, Duke explained that, pursuant to its contractual agreement with Hema Metrics, it had the right to proceed with publication of the abstract. *See id.* at 2-3. In closing, Duke provided: "Based upon the above responses to your comments, and the publication rights protected by the agreement, we are comfortable that it is proper to proceed with submitting the abstract." *Id.* at 3.

On June 9, 2003, a lawyer for Hema Metrics, Mark I. Baseman, sent a letter to Drs. Robert Califf and Donal Redden, again demanding that Duke not submit the abstract to ASN until "Hema Metrics has had a full opportunity to review the results of the study." (A copy of

this letter is attached as Exhibit H to Califf Decl. ("Baseman Letter").) Relying on section 8 of the Agreement, Baseman asserted that Duke did not have the right to publish the results of its study in its sole discretion, and, citing section 7 of the Agreement, stated that Hema Metrics withheld its consent to the publication of any Hema Metrics' proprietary information. *See* Baseman Letter at 2. Baseman stated: "If this matter cannot be resolved amicably, Hema Metrics will have no choice but to protect its legal rights . . . ." *Id.* at 3.

On June 17, 2003, Ralph McCaughan, Associate University Counsel for Duke University, discussed with Baseman the issues raised in Baseman's letter. McCaughan indicated that Duke preferred to meet in person with Hema Metrics representatives, rather than to simply have a discussion by conference call. He advised Baseman that arrangements for this call should be made with Dr. Robert Califf, MD, Director of Duke Clinical Research Institute, as this was an academic issue. McCaughan also advised Baseman that Duke was proceeding to work on the abstract, and would decide whether to submit it on June 24.

Hema Metrics did not schedule a meeting. Instead, on June 18, Hema Metrics filed this action against Duke and DCRI, seeking to restrain or enjoin Duke from submitting its abstract to ASN.

ARGUMENT

I. THE INJUNCTIVE RELIEF THAT PLAINTIFF SEEKS WOULD BE AN UNCONSTITUTIONAL PRIOR RESTRAINT

Apart from anything else, the First Amendment defeats Hema Metrics' motion because the relief sought would be an unconstitutional prior restraint. *See, e.g., Robinson v. American Broadcasting Cos., Inc.*, 441 F.2d 1396, 1399 (6th Cir. 1971) ("The injunction sought in the

present case would be a ban on speech. Not only would freedom of speech be 'chilled' – it would be totally squelched by the injunction plaintiffs have requested."); *Queen v. Tennessee Valley Auth.*, 508 F. Supp. 532, 536 (E.D. Tenn. 1980) ("The free discussion of matters of public interest is not properly enjoined.") (citations omitted), *aff'd*, 689 F.2d80 (6th Cir. 1982). Accordingly, Hema Metrics is not entitled to the relief it seeks.

The First Amendment protects Duke's interest in publishing the results of its scientific study: "It is equally settled, . . . though less commonly the subject of litigation, that the First Amendment protects scientific expression and debate just as it protects political and artistic expression." *Stanford Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991) (citations omitted). The injunction that Hema Metrics demands would quash public debate over the practical merits of its Crit Line device and the results of DCRI's research study and, thus, offends the fundamental principles of freedom of speech enunciated by Justice Hughes in the landmark case of *Near v. Minnesota*, 283 U.S. 697 (1931). *Accord New York Times v. United States*, 403 U.S. 713, 714 (1971) ("Any system of prior restraints of expression comes to this Court bearing a heavy presumption against its constitutional validity.") (citations omitted); *Ford Motor Co. v. Lane*, 67 F. Supp. 2d 745, 751 (E.D. Mich. 1999) ("The *Near* Court explained that prior restraints may be issued only in rare and extraordinary circumstances, such as when necessary to prevent the publication of troop movements during time of war, to prevent the publication of obscene material, and to prevent the overthrow of the government."); *Krebiozen Res. Found. v. Beacon Press, Inc.*, 134 N.E.2d 1, 8 (Mass.) ("[A]llowing prior restraint, provided only a judge is convinced of the falsity of the proposed publication, amounts to unconstitutional censorship."), *cert. denied*, 332 U.S. 848 (1956). Hema Metrics cannot block the dissemination

of the CLIMB study abstract through judicial order without running afoul of the First Amendment. Furthermore, even a "short term" restraint by the court would be unconstitutional. *See New York Times*, 403 U.S. at 724-25 (Brennan, J. concurring) ("[O]ur judgments in the present cases may not be taken to indicate the propriety, in the future, of issuing temporary stays and retraining order to block the publication of material sought to be suppressed by the Government."); *Ford*, 67 F. Supp. 2d at 751 ("Even a temporary restraint on pure speech is improper absent the 'most compelling circumstances.'") (citation omitted).

II. PLAINTIFF HAS SHOWN NO ENTITLEMENT TO PRELIMINARY RELIEF

Even if the First Amendment did not bar the motion, plaintiff cannot satisfy the standards in *Dominion Video Satellite, Inc. v. Echostar Satellite Corp.*, 269 F.3d 1149 (10th Cir. 2001), for temporary injunctive relief.

A. There Is No Probability That Hema Metrics Will Succeed On The Merits

Betraying its weakness, Hema Metrics asserts that it need not show much on probability of success since it allegedly has "establish[ed] the first three prongs of the four-part test for a preliminary injunction." Pl. Br. at 6. As shown below, Hema Metrics cannot establish the other elements, and even if it could, it is clear that there is nothing "serious, substantial, difficult and doubtful" about the merits of plaintiff's claims. Unhappy with the results of the CLIMB study, Hema Metrics asserts a purported contract right to stop Duke from publishing its results. There is no such contract right, despite Hema Metrics' efforts to cobble one together by quoting bits and pieces of contract language out of context. What is obvious when the contracts are read in their entirety is that Hema Metrics assumed the risk that the independent study it commissioned would not be favorable to its product and that Duke would share the study results with the

general public and the scientific community through publication. There is nothing in the plain language of either contract at issue that gives Hema Metrics the right to veto Duke's publication efforts, and no provision in either contract would be "breached' by Duke's submission of an abstract to ASN.

According to Hema Metrics, pursuant to section 6 of the Agreement, it "owns all data resulting from the Study." Pl. Br. at 7. This is wrong. The only things that Hema Metrics owns as a result of section 6 are the "Case Reports and Interim Reports, and any other reports prepared as part of the Study." Agreement § 6.1. There is no allegation that DCRI is about to disseminate such a report. Section 6.1 does not specify who owns the data, but simply provides that "[a]ll clinical data . . . will be promptly and fully disclosed to SPONSOR, and shall be freely usable by SPONSOR consistent with good business judgment." *Id.* Furthermore, regardless of Hema Metrics' ownership of the Case Reports and Interim Reports, section 6.1 explicitly provides that "***DUKE shall be free*** to maintain copies of all such materials and ***to use the results of the research and clinical study for their own . . . publication purposes*** . . . ." *Id.* (emphasis added). Section 6.1, therefore, affords Hema Metrics no prerogative to stop the submission of the abstract.

In addition, Hema Metrics ignores the fact that section 6 of the Agreement is no longer operative. The term of the Agreement was from November 1, 1999 through November 30, 2000, and therefore it has expired. *See* Agreement § 1.4 Although certain provisions of the Agreement survive expiration, section 6 is not one of them. *See id.* § 14.

Hema Metrics points to the confidentiality provisions in section 7 of the Agreement as the basis for its purported right to silence Duke, but that provision likewise is unavailing. In the

first place, "confidential information" is defined as information "clearly identified as 'Confidential' by the transmitting party at the time of disclosure." Agreement § 7. Hema Metrics adduces no evidence that the abstract contains or refers to any such information. Even if the abstract implicated such information, Hema Metrics has foregone any right to stop publication of it. Although "confidential information" generally cannot be disclosed "without authorization from the disclosing party," that bar is explicitly made subject to "the provisions of the section headed 'Publications' hereof . . . ." *Id.* In other words, confidential information can indeed be published as long as such publication complies with the provision on publications (section 8).[4]

Section 8 of the Agreement, in turn, also refutes Hema Metrics' position. Section 8 requires Duke to allow Hema Metrics to review proposed publications or abstracts, but nothing in that provision empowers Hema Metrics to stop a publication or submission of an abstract. All that section 8 provides is that where a proposed publication might reveal "patentable subject matter which requires protection," Hema Metrics "may require the delay of publication for a period of time not to exceed sixty (60) days for the purpose of filing patent applications." Agreement § 8. There is no claim that the abstract contains "patentable subject matter" or that

[4] Hema Metrics' invocation of the confidentiality provision of the Agreement is ironic given the fact that Hema Metrics' papers in this Court quote extensively from the Agreement – a document that is marked "confidential" and that is subject to the confidentiality provisions of section 7 – but Hema Metrics has taken no action to protect the confidentiality of such information and made no effort to give Duke prior notice of its filing. Having breached section 7 with its filings in this Court, Hema Metrics is in no position now to contend that the submission of the abstract somehow violates section 7. Moreover, Hema Metrics' efforts to label DCRI's study as "flawed" does not obscure the fact that a renowned medical research institution has made findings that are not favorable to plaintiff's product – a fact that Hema Metrics has now broadcast to the world with its filing of this lawsuit.

Hema Metrics needs to file applications for patentable material arising out of the study. Section 8 therefore is irrelevant.

Nor is Hema Metrics assisted by section 12 of the separate Study Site Agreement. That provision does permit the sponsor to delay a publication "in the event of inaccuracies or other matters which might [*inter alia*] . . . misrepresent the Sponsor's equipment, its capabilities or other data." Study Site Agreement § 12. However, Hema Metrics ignores the rest of section 12. Under that provision, if the parties disagree as to the contents of the proposed publication, they are to meet "at the Center's place of business prior to publication for the purpose of making good faith efforts to discuss and resolve any such issues of disagreement." *Id.* Duke proposed such a meeting in accordance with section 12, but Hema Metrics responded by filing this lawsuit, thereby breaching section 12 and manifesting its bad faith. Furthermore, it is absolutely clear under section 12 that even if the parties cannot resolve their differences as to the contents of a proposed publication, Duke retains the unqualified right to publish: "This [the provision for meeting and conferring] ***shall not be taken to grant Sponsor any right of editorial control over publications prepared by Center.***" *Id.* (emphasis added).

In short, the plain language of the contracts refute Hema Metrics' claim that it has the contractual right to stop submission of the abstract or publication of the results of the study. Instead, what Hema Metrics is trying to do is have the Court rewrite the parties' contract with a preliminary injunction. However, "courts must construe and enforce contracts as written, in order to preserve the fundamental right of freedom to contract." *Lexington Ins. Co. v. Tires Into Recycled Energy*, 522 S.E.2d 798, 800 (N.C. App. 1999); *accord Gaston Cty. Dyeing Mach. Co. v. Northfield Ins. Co.*, 524 S.E.2d 558, 563 (N.C. 2000); *see also Hartford Acc. & Indem. Co. v.*

U.S. Fidelity & Guar. Co., 962 F.2d 1484, 1487 (10th Cir. 1992) (applying same principles under Utah law).[5] It is not the province of the judiciary to remake the parties' bargain or impose on them contractual provisions to which they did not agree. Here, Hema Metrics bargained for an independent scientific review of its product by a renowned institution, hoping that the results would help it market the product. By the same token, consistent with its mission as an academic research institution, Duke bargained for the right to publish the results of its work. Although it hoped that the results would be otherwise, Hema Metrics assumed the risk that the results of the research might be negative, as well as the risk that Duke would publish them. This was an arm's length transaction between sophisticated parties, and Hema Metrics should be held to the terms of the bargain that it struck with Duke.

B. Hema Metrics Has Not Demonstrated Any Threat Of Irreparable Harm

If Hema Metrics is to be believed, it will go out of business on Thursday if injunctive relief is denied and the abstract is submitted to ASN. *See* Pl. Br. at 3 (implying "threat to a company's viability"). Despite plaintiff's exaggerations, the record reveals no evidence of significant harm, much less irreparable injury. All that is scheduled to happen before June 25 is the submission of an abstract to ASN for peer review by scientific practitioners who are under strict obligations of confidentiality. In the short run, there will be no dissemination of the abstract beyond this limited audience. Hema Metrics cites no evidence to the contrary. Indeed, since Hema Metrics claims to employ "highly skilled researchers and clinicians with considerable experience," Declaration of David A. Bell ¶ 18, then Hema Metrics is well aware of

[5] The Agreement is governed by North Carolina law. *See* Agreement ¶ 21. The Study Site Agreement is governed by Utah law. *See* Study Site Agreement ¶ 20.

the fact that the peer review process of reviewing abstracts like the one in question is a confidential process. Moreover, if the CLIMB study results really were as scientifically "flawed" as Hema Metrics claims, then this surely would be apparent to the ASN peer reviewers to whom the abstract would be submitted. In no case does submission of the abstract for confidential peer review irreparably injure Hema Metrics.

Furthermore, the type of injury that Hema Metrics claims – potential injury to business reputation and loss of sales due to negative study findings – is not the type of harm that supports preliminary injunctive relief. Alleged loss of income and harm to reputation "falls far short of the type of irreparable injury which is a necessary predicate to the issuance of a temporary injunction." *Sampson v. Murray*, 415 U.S. 61, 91-92 (1974). Even if Hema Metrics were correct that Duke somehow breached the Agreement by producing a "flawed" study, Hema Metrics has not demonstrated the lack of an adequate legal remedy in damages. Furthermore, the potential consequences that Hema Metrics complains of are risks it assumed when it subjected its product to independent scientific review by an outside organization. It was clearly foreseeable that the results of the study – which Duke unambiguously retained the contractual right to publish – could be negative and could adversely affect Hema Metrics' sales and business reputation.

C. The Countervailing Harm To Duke Of An Injunction Outweighs The Purported Injury Claimed by Plaintiff In The Absence Of One

In contrast to the nebulous "injury" that Hema Metrics claims it will suffer if the abstract is submitted to ASN, the harm to Duke if an injunction is issued restraining submission of the abstract is clear. The ASN conference is the key scientific meeting in the field of nephrology and is conducted only once a year. The deadline for submission of abstracts to be included in the conference is midnight on June 25. Defendants have no control over this deadline; it was established by ASN. If the deadline is missed due to the issuance of an injunction against defendants, then Duke and DCRI will not be able to make presentations at the conference because they would not have submitted an abstract for pre-conference peer review. This deadline, once it expires, is gone and cannot be called back by the Court – even if the Court were later to agree with Duke that Hema Metrics' contract claims have no merit.

This, of course, is exactly what Hema Metrics evidently hopes will happen – that the Court will enjoin submission of the abstract so that, regardless of what transpires during the rest of the case, defendants will not be able to participate in the ASN conference this year. But it this is precisely why the injunction that Hema Metrics seeks is inappropriate. It would have the effect of providing Hema Metrics "all the relief it could feasibly attain after a full trial on the merits." *Dominion Video*, 269 F.3d at 1155. The Tenth Circuit "disfavors such injunctions," permitting them only when the movant has discharged "a heightened burden of showing that the traditional four factors ***weigh heavily and compellingly in its favor***." *Id.* (emphasis added). Hema Metrics has not even come close to making such a heightened showing.

D. The Pubic Interest Weighs Strongly Against The Injunctive Relief Sought

Hema Metrics gives this factor short shrift, arguing that Duke should be silenced with a court order because "otherwise the public would be exposed to and may rely upon flawed and misleading research" and, because principles of free speech and academic freedom allegedly are irrelevant here since DCRI got paid to do the research. Pl. Br. at 5-6. These arguments simply illustrate why an injunction should be denied.

Hema Metrics seeks to have this Court sit as a super "censor board" and suppress the publication of study results that Hema Metrics bargained for but does not like. No public interest is served by such suppression. Here, a study conducted pursuant to the parties' agreement by a renowned academic research institution raises questions about the efficacy of a medical device in terms of, *inter alia*, incidence of hospitalization and death. From the standpoint of patient care and safety, health care providers and patients alike have a vital interest in being apprised of such information. The fact that, as Hema Metrics claims, the device has been approved by the Food and Drug Administration, Pl. Br. at ii, is all the more reason why the results of the DCRI study should be disseminated. Such governmental approval, which Hema Metrics evidently relies upon to tout its product, may be misleading unless the complete picture on this device is known.

Furthermore, Hema Metrics' unsubstantiated claims that the research was "flawed" and the results "anomalous," Pl. Br. ii, even if true, are no basis for suppressing the study with an injunction. If the study has deficiencies (and it does not), that fact should be exposed through debate and a free exchange of ideas at a peer-reviewed scientific conference such as the one to be conducted this fall by ASN. The matter should not be resolved by an injunction that silences debate on this issue.

E. Relevant Case Law Militates Against The Injunctive Relief Sought

Hema Metrics cites no case in which a court has enjoined the publication of a scientific study about a medical device that raises issues about patient care and safety on the strength of the manufacturer's claim that the study is "flawed" and "anomalous." Cases in which this subject has arisen reject Hema Metrics' position.

For example, in *Krebiozen*, the manufacturer of a cancer drug sought to enjoin publication of a book which suggested that the drug was not as effective as it had been represented to be, alleging that the book contained "false, fraudulent, wrongful, malicious and erroneous statements" and that publication would "cause irreparable damage to the professional reputations of the plaintiffs . . . and that the trade name of the drug will be irreparably injured." 134 N.E.2d at 3. Assuming these allegations to be true, the court nonetheless affirmed denial of the injunction:

> The establishment of the truth about Krebiozen as soon as possible is critically important to the public. If it is a cure, it will be one of the great discoveries of modern times; if it is of value in some cases only the limitations are important; if it is of no value lives may be saved and suffering avoided by the establishment of the fact. . . . It is axiomatic in our society that full information and free discussion are important in the search for wise decisions and best courses of action. . . . We grant that it could conceivably be here, as claimed, that this attack . . . will impede progress in the testing of Krebiozen. But basing a rule on that possibility would end or at least effectively emasculate discussion in the very controversial fields where it is most important.

Id. at 7.[6]

[6] *See also Halikas v. University of Minnesota*, 856 F. Supp. 1331, 1336 (D. Minn. 1994) (denying request to enjoin dissemination of a university's critical review of an investigator's research; "the public has a great interest in maintaining the integrity of institutional research on human subjects. . . . [B]arring the IRB from transmitting the results of its investigation would endanger the public and hinder this essential function"); *cf. Stanford*, 773 F. Supp. at 474, 478 (invalidating a proposed grant provision that would have given the government the right to control the dissemination of research results that the government might conclude are "preliminary" or "unvalidated:" "Stanford

CONCLUSION

Plaintiff's motion should be denied.

This, the 23rd of June, 2003.

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University, a premier academic institution, engaged in significant scientific and medical research for the benefit of the American people, is not ipso facto compelled under the law to surrender is free speech rights and those of its scientific researchers to a 'contracting officer' merely because a regulation issued by defendants so directs").

CERTIFICATE OF SERVICE

I hereby certify that a copy of Defendants' Memorandum in Opposition to Plaintiff's Motion for a Temporary Restraining Order and Preliminary Injunction, Declaration of Ralph McCaughan, and Declaration of Robert M. Califf, together with supporting exhibits, was served on the following parties by the means indicated, this the 23rd day of June, 2003:

HAND DELIVERED:

Terry E. Welch
Bentley J. Tolk
Timothy B. Smith
Parr, Waddoups Brown Gee & Loveless
Suite 1300
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Salt Lake City, UT 84111-1537

VIA FIRST CLASS MAIL, POSTAGE PREPAID:

Meryl Macklin
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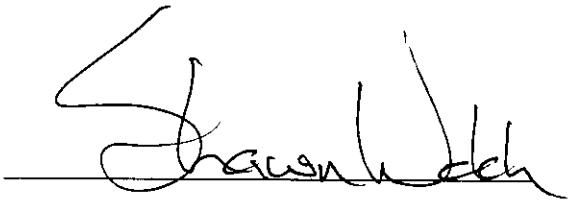

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